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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,175	DOUNG ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-9 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5-9 and 24-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 November 2003 has been entered.

Status of the Claims

2. This action is in response to papers filed 19 November 2003 in which claims 6, 28 and 29 were amended and claims 32-35 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 23 July 2003, not reiterated below are withdrawn in view of the amendments and new grounds for rejection. All of the arguments have been thoroughly reviewed and are discussed below as they apply to the instant rejection. New grounds for rejection are discussed.

Information Disclosure Statement

3. The references listed on the 1449 received 24 November 2003 have been reviewed and considered. Any references lined through have previously been considered as indicated on 1449 filed previously.

Election/Restrictions

4. Newly submitted claim 35 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The invention originally claimed and the newly claimed invention are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product i.e. the newly claimed process can be practiced with any bottom-filling tank and does not require the substrate comprising electrodes, self-assembled monolayer and capture binding ligand required in the originally claimed invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 35 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim 35 is withdrawn from prosecution.

Claims 2-3, 5-9 and 24-34 are under prosecution.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "wherein the cap is removable" is added to the new claim 34. However, the specification fails to define or provide any disclosure to support such claim recitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States

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before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 24, 2, 3, 5, 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Burns et al (U.S. Patent No. 6,379,929, filed 19 November 1997).

Regarding Claim 24, Burns et al disclose a biochip cartridge comprising a reaction chamber comprising a substrate comprising a printed circuit board comprising an array of electrodes (Column 42, lines 10-20) the electrodes comprising a self-assembled monolayer and capture binding ligand (Column 26, lines 59-67), an inlet port for the introduction of reagents (column 6, lines 18-32) and interconnects to allow electrical connection of the electrodes to a processor (Column 42, lines 10-20).

Regarding Claim 2, Burns et al disclose the biochip wherein the binding ligands comprising nucleic acids (Column 47, lines 12-34).

Regarding Claim 3, Burns et al disclose the biochip wherein the chamber further comprises a gasket (i.e. capillary valve) to retain fluid in contact with the array (Column 8, lines 35-49).

Regarding Claim 5, Burns et al disclose the biochip wherein the reaction chamber further comprises an outlet port (Column 6, lines 32-35).

Regarding Claim 7, Burns et al disclose the biochip wherein the array is on one surface of the substrate i.e. one wafer (Column 21, lines 49-59; Column 42, lines 10-20 and Fig. 2).

Regarding Claim 8, Burns et al disclose the biochip wherein two surfaces of the substrate comprises an array i.e. arrays on each side (surface) of the glass wafer (Column 41, lines 51-61 and Fig. 2B).

Response to Arguments

9. Applicant argues that Burns et al do not teach an array of electrodes each comprising a self-assembled monolayer and a capture binding ligand but instead teaches a channel,

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portions of which may be coated with a self-assembled monolayer. The argument has been considered but is not found persuasive because a careful reading of the cited passage reveals that Burn et al teach the channel comprises electrodes (Column 26, lines 51-55 and Column 42, lines 17-20) and the surface of the channel is coated with the self-assembled monolayer (Column 26, lines 59-62). As such, Burns et al teach the electrodes as claimed.

Applicant further argues that Burns et al do not teach an electrode comprising a capture binding ligand. The argument has been considered but is not found persuasive because as applicant notes, Burns et al teach that one or more of the reagents e.g. nucleotides, primers, DNA, enzymes etc are operably or functionally connected to the substrate (i.e. channel) (Column 47, lines 12-26). And as noted above, Burns et al teach the substrate (i.e. channel) comprises electrodes (Column 26, lines 51-55 and Column 42, lines 17-20). The claims do not require that the binding ligand be covalently coupled directly to the electrode but merely that the electrodes comprise binding ligands. Because Burns et al teach the channel comprises electrodes and binding ligands are functionally or operably connected to the channel, they teach the electrodes comprising binding ligands as claimed.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 6 and 2, 3, 5, 7, 8 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al (U.S. Patent No. 6,051,380, issued 18 April 2000) in view of and Eckhardt et al (U.S. Patent No. 6,127,127, issued 3 October 2000) and Besemer et al (U.S. Patent No. 5,945,334, issued 31 August 1999).

Regarding Claim 6, Sosnowski et al teach a biochip cartridge comprising a reaction chamber comprising a substrate comprising an array of electrodes (Column 26, line 49-Column 27, line 18) comprising a binding surface comprising linear molecules arranged perpendicular to the surface (Column 25, lines 46-55) and a capture binding ligand (Column 28, lines 1-66). They teach the cartridge further comprising an inlet port (Column 63, lines 18-20) and interconnects to all electrical connection of the electrodes to a processor (Column 61, lines 25-33). Sosnowski et al do not specifically teach the linear molecule binding surface is a self-assembled monolayer (SAM). However, SAM was well known in the art as a preferred binding surface at the time the claimed invention was made as taught by Eckhardt et al who teach that SAM on an electrode provides a surface that is thermally stable, oxidation resistant and is formed rapidly and reproducibly (Column 3, lines 57-59). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the binding surface of Sosnowski et al with the similar SAM of Eckhardt et al providing a thermally stable, oxidation resistant surface which is formed rapidly and reproducibly (Eckhardt et al, Column 3, lines 57-59).

Sosnowski et al teach the chamber comprises an inlet port (Column 63, lines 18-20) but they do not teach an inlet port positioned at the bottom of the chamber and an outlet port positioned at the top of the chamber. However, Besemer et al teach a similar chamber wherein the inlet and outlet ports are positioned as claimed whereby fluid circulation within the chamber is improved thereby increasing hybridization rate (Fig. 5 and Column 7, lines 6-26).

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to position inlet and outlet ports at the most upper and lower ends of the chamber of Sosnowski et al as taught by Besemer et al for the expected benefit of improved fluid flow and increased hybridization rate as taught by Besemer et al (Column 7, lines 6-26).

Regarding Claim 2, Sosnowski et al teach the ligand comprise nucleic acids (Column 15, lines 40-46).

Regarding Claim 3, Sosnowski et al teach the cartridge is in a seal environment (Column 63, lines 18-20) but they do not specifically teach the gasket provides the seal. However, Besemer et al teach the similar cartridge wherein a gasket provides the sealing environment (Column 10, lines 13-24). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize a gasket to provide the sealed environment of Sosnowski based on the well known use of gaskets for sealing as taught by Besemer et al (Column 10, lines 13-24).

Regarding Claim 5, Sosnowski et al teach the cartridge comprises a port (Column 63, lines 18-20) and they further teach that fluids are removed from the cartridge (e.g. Column 65, lines 58-60) but they do not specifically teach an outlet port. However, Besemer et al teach the similar cartridge wherein the outlet port is useful for removing fluids (Column 7, lines 6-18). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known outlet port of Besemer to the cartridge of Sosnowski based on the usefulness taught by Besemer.

Regarding Claim 7, Sosnowski et al teach the cartridge wherein the array is on one surface of the substrate (Column 23, lines 46-60).

Regarding Claim 8, Sosnowski et al teach the cartridge comprises two surfaces each comprising an array (Column 23, lines 62-67).

Regarding Claim 31, Sosnowski et al teach the cartridge wherein the binding ligands are proteins (Column 15, lines 40-46).

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Regarding Claims 32-33, Sosnowski et al teach the cartridge comprises a port (Column 63, lines 18-20) but they do not teach separated inlet and outlet ports. However, Besemer et al teach the similar cartridge wherein separated inlet and outlet ports which are connected via the cartridge are useful for introducing and removing fluids (Column 7, lines 6-18). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known inlet and outlet ports of Besemer to the cartridge of Sosnowski based on the usefulness taught by Besemer.

12. Claims 9 and 34 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al (U.S. Patent No. 6,051,380, issued 18 April 2000) in view of and Eckhardt et al (U.S. Patent No. 6,127,127, issued 3 October 2000) and Besemer et al (U.S. Patent No. 5,945,334, issued 31 August 1999) as applied to Claim 6 above and further in view of and further in view of Anderson et al (U.S. Patent No. 6,326,211, filed 27 June 1996).

Regarding Claims 9 and 34, Sosnowski et al teach the cartridge comprising a port within a sealed environment for reagent introduction (Column 63, lines 13-24) but they do not teach a cap including a storage well in the cap. However, means for introducing reagents into a cartridge comprising a storage well in a cartridge cap was known in the art at the time the claimed invention was made as taught by Anderson et al.

Anderson et al teach a similar cartridge comprising a reaction chamber and interconnects, the reaction chamber comprising a substrate and an inlet port and electrodes wherein the substrate comprises a capture binding ligand (Column 2, line 22-51) and further comprising means for introducing reagents into the cartridge wherein the means comprises a cap (well #510 illustrated in the top portion of the cartridge illustrated in Fig. 5B) comprising at

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least one storage well comprising assay reagents (Column 24, lines 44-65 and Fig. 5 A & B) wherein the arrangement of storage wells adjacent to the substrate provides easy access to reagents and convenient storage reagents (Column 25, lines 42-52). Furthermore, disassembly of the cartridge would remove the cap thereby providing a removable cap as claimed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the cap comprising a storage well as taught by Anderson et al to the cartridge of Sosnowski et al for the expected benefits of easy access to reagents and convenient storage reagents as taught by Anderson et al (Column 25, lines 42-52).

Regarding Claim 25, Sosnowski et al teach the chamber comprising an inlet port is in a sealed relationship with the chamber (Column 63, lines 18-20) but they do not specifically teach the inlet comprises a valve including a semipermeable membrane.

However, valves comprising semipermeable membranes were well known and routinely practiced in the art at the time the claimed invention was made as taught by Anderson et al (Column 36, lines 47-65) who further teach that valves comprising membranes are preferred for controlling fluid flow. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the valve of Sosnowski et al by incorporating a valve with a semipermeable membrane as taught by Anderson et al based on the preferred teaching of Anderson et al (Column 36, lines 47-65).

13. Claims 24 and 2, 7, 8, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al (U.S. Patent No. 6,051,380, issued 18 April 2000) in view of and Eckhardt et al (U.S. Patent No. 6,127,127, issued 3 October 2000).

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Regarding Claim 24, Sosnowski et al teach a biochip cartridge comprising a reaction chamber comprising a substrate comprising a printed circuit board comprising an array of electrodes (Column 26, line 49-Column 27, line 18) wherein each electrode comprises a binding surface comprising linear molecules arranged perpendicular to the surface (Column 25, lines 46-55) and a capture binding ligand (Column 28, lines 1-66). They teach the cartridge further comprising an inlet port (Column 63, lines 18-20) and interconnects to all electrical connection of the electrodes to a processor (Column 61, lines 25-33). Sosnowski et al do not specifically teach the linear molecule binding surface is a self-assembled monolayer (SAM). However, SAM was well known in the art as a preferred binding surface at the time the claimed invention was made as taught by Eckhardt et al who teach that SAM on an electrode provides a surface that is thermally stable, oxidation resistant and is formed rapidly and reproducibly (Column 3, lines 57-59). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the binding surface of Sosnowski et al with the similar SAM of Eckhardt et al providing a thermally stable, oxidation resistant surface which is formed rapidly and reproducibly (Eckhardt et al, Column 3, lines 57-59).

Regarding Claim 2, Sosnowski et al teach the ligand comprise nucleic acids (Column 15, lines 40-46).

Regarding Claim 7, Sosnowski et al teach the cartridge wherein the array is on one surface of the substrate (Column 23, lines 46-60).

Regarding Claim 8, Sosnowski et al teach the cartridge comprises two surfaces each comprising an array (Column 23, lines 62-67).

Regarding Claim 31, Sosnowski et al teach the cartridge wherein the binding ligands are proteins (Column 15, lines 40-46).

14. Claims 3, 5, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al (U.S. Patent No. 6,051,380, issued 18 April 2000) in view of and Eckhardt et al (U.S. Patent No. 6,127,127, issued 3 October 2000) as applied to Claim 24 above and further in view of Besemer et al (U.S. Patent No. 5,945,334, issued 31 August 1999).

Regarding Claim 3, Sosnowski et al teach the cartridge is in a seal environment (Column 63, lines 18-20) but they do not specifically teach the a gasket provides the seal. However, Besemer et al teach the similar cartridge wherein a gasket provides the sealing environment (Column 10, lines 13-24). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize a gasket to provide the sealed environment of Sosnowski based on the well known use of gaskets for sealing as taught by Besemer et al (Column 10, lines 13-24).

Regarding Claim 5, Sosnowski et al teach the cartridge comprises a port (Column 63, lines 18-20) and they further teach that fluids are removed from the cartridge (e.g. Column 65, lines 58-60) but they do not specifically teach an outlet port. However, Besemer et al teach the similar cartridge wherein the outlet port is useful for removing fluids (Column 7, lines 6-18). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known outlet port of Besemer to the cartridge of Sosnowski based on the usefulness taught by Besemer.

Regarding Claims 32-33, Sosnowski et al teach the cartridge comprises a port (Column 63, lines 18-20) but they do not teach separated inlet and outlet ports. However, Besemer et al teach the similar cartridge wherein separated inlet and outlet ports which are connected via the cartridge are useful for introducing and removing fluids (Column 7, lines 6-18). It would

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have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known inlet and outlet ports of Besemer to the cartridge of Sosnowski based on the usefulness taught by Besemer.

15. Claims 9 and 34 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al (U.S. Patent No. 6,051,380, issued 18 April 2000) in view of and Eckhardt et al (U.S. Patent No. 6,127,127, issued 3 October 2000) as applied to Claim 24 above and further in view of Anderson et al (U.S. Patent No. 6,326,211, filed 27 June 1996).

Regarding Claims 9 and 34, Sosnowski et al teach the cartridge comprising a port within a sealed environment for reagent introduction (Column 63, lines 13-24) but they do not teach a cap including a storage well in the cap. However, means for introducing reagents into a cartridge comprising a storage well in a cartridge cap was known in the art at the time the claimed invention was made as taught by Anderson et al.

Anderson et al teach a similar cartridge comprising a reaction chamber and interconnects, the reaction chamber comprising a substrate and an inlet port and electrodes wherein the substrate comprises a capture binding ligand (Column 2, line 22-51) and further comprising means for introducing reagents into the cartridge wherein the means comprises a cap (well #510 illustrated in the top portion of the cartridge illustrated in Fig. 5B) comprising at least one storage well comprising assay reagents (Column 24, lines 44-65 and Fig. 5 A & B) wherein the arrangement of storage wells adjacent to the substrate provides easy access to reagents and convenient storage reagents (Column 25, lines 42-52). Furthermore,

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disassembly of the cartridge would remove the cap thereby providing a removable cap as claimed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the cap comprising a storage well as taught by Anderson et al to the cartridge of Sosnowski et al for the expected benefits of easy access to reagents and convenient storage reagents as taught by Anderson et al (Column 25, lines 42-52).

Regarding Claim 25, Sosnowski et al teach the chamber comprising an inlet port is in a sealed relationship with the chamber (Column 63, lines 18-20) but they do not specifically teach the inlet comprises a valve including a semipermeable membrane.

However, valves comprising semipermeable membranes were well known and routinely practiced in the art at the time the claimed invention was made as taught by Anderson et al (Column 36, lines 47-65) who further teach that valves comprising membranes are preferred for controlling fluid flow. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the valve of Sosnowski et al by incorporating a valve with a semipermeable membrane as taught by Anderson et al based on the preferred teaching of Anderson et al (Column 36, lines 47-65).

16. Claims 26 and 2, 7-9, 27-31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al (U.S. Patent No. 6,051,380, issued 18 April 2000) in view of and Eckhardt et al (U.S. Patent No. 6,127,127, issued 3 October 2000) and Anderson et al (U.S. Patent No. 6,326,211, filed 27 June 1996).

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Regarding Claim 26, Sosnowski et al teach a biochip cartridge comprising a reaction chamber comprising a substrate comprising an array of electrodes (Column 26, line 49-Column 27, line 18) comprising a binding surface comprising linear molecules arranged perpendicular to the surface (Column 25, lines 46-55) and a capture binding ligand (Column 28, lines 1-66). They teach the cartridge further comprising an inlet port (Column 63, lines 18-20) and interconnects to all electrical connection of the electrodes to a processor (Column 61, lines 25-33). Sosnowski et al do not specifically teach the linear molecule binding surface is a self-assembled monolayer (SAM). However, SAM was well known in the art as a preferred binding surface at the time the claimed invention was made as taught by Eckhardt et al who teach that SAM on an electrode provides a surface that is thermally stable, oxidation resistant and is formed rapidly and reproducibly (Column 3, lines 57-59). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the binding surface of Sosnowski et al with the similar SAM of Eckhardt et al providing a thermally stable, oxidation resistant surface which is formed rapidly and reproducibly (Eckhardt et al, Column 3, lines 57-59).

Sosnowski et al teach the chamber comprising an inlet port is in a sealed relationship with the chamber (Column 63, lines 18-20) but they do not specifically teach the inlet comprises a valve including a semipermeable membrane.

However, valves comprising semipermeable membranes were well known and routinely practiced in the art at the time the claimed invention was made as taught by Anderson et al (Column 36, lines 47-65) who further teach that valves comprising membranes are preferred for controlling fluid flow. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the valve of Sosnowski et al by incorporating a valve with a semipermeable membrane as taught by Anderson et al based on the preferred teaching of Anderson et al (Column 36, lines 47-65).

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Regarding Claim 2, Sosnowski et al teach the ligand comprise nucleic acids (Column 15, lines 40-46).

Regarding Claim 7, Sosnowski et al teach the cartridge wherein the array is on one surface of the substrate (Column 23, lines 46-60).

Regarding Claim 8, Sosnowski et al teach the cartridge comprises two surfaces each comprising an array (Column 23, lines 62-67).

Regarding Claims 9 and 34, Sosnowski et al teach the cartridge comprising a port within a sealed environment for reagent introduction (Column 63, lines 13-24) but they do not teach a cap including a storage well in the cap. However, means for introducing reagents into a cartridge comprising a storage well in a cartridge cap was known in the art at the time the claimed invention was made as taught by Anderson et al.

Anderson et al teach a similar cartridge comprising a reaction chamber and interconnects, the reaction chamber comprising a substrate and an inlet port and electrodes wherein the substrate comprises a capture binding ligand (Column 2, line 22-51) and further comprising means for introducing reagents into the cartridge wherein the means comprises a cap (well #510 illustrated in the top portion of the cartridge illustrated in Fig. 5B) comprising at least one storage well comprising assay reagents (Column 24, lines 44-65 and Fig. 5 A & B) wherein the arrangement of storage wells adjacent to the substrate provides easy access to reagents and convenient storage reagents (Column 25, lines 42-52). Furthermore, disassembly of the cartridge would remove the cap thereby providing a removable cap as claimed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the cap comprising a storage well as taught by Anderson et al to the cartridge of Sosnowski et al for the expected benefits of easy access to reagents and convenient storage reagents as taught by Anderson et al (Column 25, lines 42-52).

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Regarding Claims 27-28, Anderson et al further teach the membrane allows escape of gas while retaining the sample fluid e.g. Teflon (Column 22, lines 6-17 and Fig. 2B). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the Teflon membrane of Anderson et al to the cartridge of Burns et al to for the expected benefit of permitting the escape of any displaced gas from the chamber as taught by Anderson et al (Column 22, lines 6-9)

Regarding Claim 29, Anderson et al further teach the membrane allows escape of gas while retaining the sample fluid e.g. Teflon (Column 22, lines 6-17 and Fig. 2B) but they do not teach the permeable membrane is Gortex™. However, the specification teaches that Teflon and Gortex™ are functional equivalents (page 13, second paragraph).

For example, a semi-permeable membrane or filter may be used, that preferentially allows the escape of gas but retains the sample fluid in the chamber. For example, porous teflons such as Gortex™ allow air but not fluids to penetrate.

The courts have stated with regard to homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904). Therefore, based on the functional equivalency of Teflon and Gortex™ one of ordinary skill in the art would have been motivated to substitute Gortex™ for the Teflon of Anderson et al because one of ordinary skill would have expected the two membranes to function in an equivalent manner.

Regarding Claim 30, Sosnowski et al teach the cartridge wherein the substrate comprises a printed circuit board (Column 26, line 49-Column 27, line 18).

Regarding Claim 31, Sosnowski et al teach the cartridge wherein the binding ligands are proteins (Column 15, lines 40-46).

17. Claims 3, 5, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al (U.S. Patent No. 6,051,380, issued 18 April 2000) in view of and Eckhardt et al (U.S. Patent No. 6,127,127, issued 3 October 2000) and Anderson et al (U.S. Patent No. 6,326,211, filed 27 June 1996) as applied to Claim 26 above and further in view of Besemer et al (U.S. Patent No. 5,945,334, issued 31 August 1999).

Regarding Claim 3, Sosnowski et al teach the cartridge is in a seal environment (Column 63, lines 18-20) but they do not specifically teach the a gasket provides the seal. However, Besemer et al teach the similar cartridge wherein a gasket provides the sealing environment (Column 10, lines 13-24). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize a gasket to provide the sealed environment of Sosnowski based on the well known use of gaskets for sealing as taught by Besemer et al (Column 10, lines 13-24).

Regarding Claim 5, Sosnowski et al teach the cartridge comprises a port (Column 63, lines 18-20) and they further teach that fluids are removed from the cartridge (e.g. Column 65, lines 58-60) but they do not specifically teach an outlet port. However, Besemer et al teach the similar cartridge wherein the outlet port is useful for removing fluids (Column 7, lines 6-18). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known outlet port of Besemer to the cartridge of Sosnowski based on the usefulness taught by Besemer.

Regarding Claims 32-33, Sosnowski et al teach the cartridge comprises a port (Column 63, lines 18-20) but they do not teach separated inlet and outlet ports. However, Besemer et al teach the similar cartridge wherein separated inlet and outlet ports which are connected via the cartridge are useful for introducing and removing fluids (Column 7, lines 6-18). It would

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have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known inlet and outlet ports of Besemer to the cartridge of Sosnowski based on the usefulness taught by Besemer.

Conclusion

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741 until 13 January 2004. The examiner can normally be reached on 6:00 TO 3:30 Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-0507.



BJ Forman, Ph.D.
Primary Examiner
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